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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,992	03/15/2004	Gary J. Beck	D-2804CON2	2049
7590 01/04/2006				
Frank J. Uxa Stout, Uxa, Buyan & Mullins, LLP Suite 300 4 Venture Irvine, CA 92618		EXAMINER JAGOE, DONNA A		
		ART UNIT 1614		
		PAPER NUMBER		
DATE MAILED: 01/04/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/800,992	BECK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

The amendment filed 6 October 2005 has been received and entered. Claim 32 has been amended. Claims 31-50 are pending to which the following grounds of rejection are or remain applicable.

### ***Response to Amendment***

Objection of claim 32 is no longer maintained in view of the amendment to the spelling of the word prednisolone.

Rejection of claims 32 and 42 under 35 U.S.C. §112 2<sup>nd</sup> paragraph is no longer maintained in view of the amendment.

### ***Response to Arguments***

Applicant's arguments filed 6 October 2005 have been fully considered but they are not persuasive. Rejection of claims 31-50 are maintained and hereby repeated.

### ***Current Rejections***

Claims 31-36, 39-46 and 49-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Loftsson U.S. 5,472,954 A.

Loftsson et al. teach an ophthalmic composition (column 18, lines 8-12) comprising a cyclodextrin, such as the sulfobutyl ether of  $\beta$  cyclodextrin (column 6, line 60) and an anti-inflammatory steroid (column 19, lines 16-39), such as prednisolone (see table 10, column 28). The ophthalmic cyclodextrin composition has water added in

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addition to the active ingredient along with pH adjusters, buffers and preservatives, in a sterile isotonic buffered aqueous solution (column 1`9, lines 24-31).

Claims 31, 36-38, and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loftsson as applied to claims 31-36, 39-46 and 49-50 above, and further in view of Dziabo et al. U.S. Patent No. 5,424,078.

Claims 37-38 are drawn to a cyclodextrin and prednisolone composition preserved with a chlorite preservative such as chloride dioxide. Loftsson et al., as disclosed above, teach a preserved cyclodextrin and prednisolone ophthalmic composition lacking the chlorite preservative.

Dziabo et al. teach an ophthalmic composition with a stabilized chloride dioxide preservative (see abstract).

It would have been made obvious to one of ordinary skill in art at the time it was made to employ chloride dioxide as a preservative in an ophthalmic preparation motivated by the teaching of Dziabo et al who employs stabilized chlorine dioxide as a preservative for ophthalmic preparations.

Applicant asserts that the prednisolone cited in Loftsson is merely "prednisolone" and the instant claims are directed to prednisolone acetates. In response, upon consultation with the Merck Index 11<sup>th</sup> edition pages, 1989, 1223-1224, the compound prednisolone appears to be synonymous with prednisolone acetate (see compound 7719, page 1223) and prednisolone sodium phosphate is a separate entity (see compound 7721, page 1224). Thus the rejection is maintained.

Regarding the 35 U.S.C. 103(a) rejection over Loftsson in view of Dziabo et al., applicant asserts that Loftsson does not cite prednisolone acetate, rather it cites "prednisolone". Again, in the Merck Index 11<sup>th</sup> edition pages, 1989, 1223-1224, the compound prednisolone appears to be synonymous with prednisolone acetate (see compound 7719, page 1223) and prednisolone sodium phosphate is a separate entity (see compound 7721, page 1224). Thus the rejection is maintained.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Merck Index, 11<sup>th</sup> edition, Merck & Co. 1989, Pages 1223-1224.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

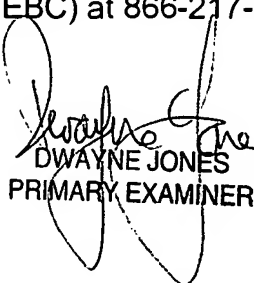
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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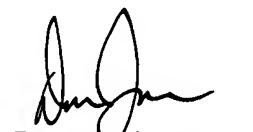
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DWAYNE JONES  
PRIMARY EXAMINER



Donna Jagoe  
Patent Examiner  
Art Unit 1614

12/27/2005